

### **Remarks**

The Applicants have cancelled Claims 1-19 without prejudice and without disclaimer of the subject matter therein. The Applicants specifically reserve the right to file one or more divisional applications directed to that subject matter.

New Claims 51-54 have been added. They are the same as Claim 50 except that they depend on Claims 44-47, respectively.

Claims 44-47 have been amended into independent form inasmuch as they are methods of treating and dependent from another method of treating for antecedent basis of a composition. The Applicants respectfully submit that placing Claims 44-47 into independent form places them into better condition for allowance. However, the scope of those claims has not changed by virtue of their being rewritten into independent form.

Claims 43-47 and 50 stand rejected under 35 U.S.C. §112, first paragraph. The Applicants note the Examiner's helpful comments concerning the alleged new matter. The Applicants also note that the phrase at issue, namely "consisting essentially of," has been interpreted as "comprising." The Applicants have accordingly amended Claim 43 to substitute "comprising" in place of "consisting essentially of." Nonetheless, for the record, the Applicants respectfully submit that use of the term "consisting essentially of" is in no way new matter. It is common practice recognized for decades that the transitional phrases may be substituted routinely without the issue of new matter being any issue at all. In any event, the Applicants respectfully submit that the rejection is now moot.

Claims 43-47 and 50 stand rejected under 35 U.S.C. §112, first paragraph with respect to enablement. The Applicants note with appreciation the Examiner's detailed comments in support of

the rejection.

The Applicants have amended Claims 43-46 to remove reference to “or preventing.” The Applicants therefore respectfully submit that the scope of the rejection is reduced and, to a large extent, rendered moot. In particular, the comments with respect to the “quantity of experimentation” in the Official Action that are directed to known cures or preventative regimens is now rendered moot.

With respect to methods of treating, the Applicants have already, in their previous Response, demonstrated that the Applicants’ Specification fully enables those skilled in the art to practice the currently claimed subject matter. In that regard, the Applicants note that methods of treating cancer are known and have been known for many years. Therefore, the issue of unpredictability associated with the “preventing” previously claimed is thereby rendered moot.

The Official Action itself recognizes that the Specification teaches “a pharmacological approach for the treatment of cancers” on Page 5 and further recognizes that the Applicants’ Specification provides examples showing that expression of zyxin EWS-Fli cell lines reduced to tumorigenicity of tumor cells.

On the other hand, the rejection takes the position that the Specification is silent with respect to the *in vivo* efficacy aspect. The Applicants respectfully submit that the Specification nonetheless provides ample guidance to one skilled in the art to practice the subject matter particularly given the high level of skill in this art, as acknowledged in the rejection (as being a PhD or MD).

The Applicants enclose a Declaration of Céline Bouquet. That Declaration contains the results of experiments conducted by the Declarant based on the Applicants’ original disclosure. In other words, the Declarant read the Applicants’ disclosure and then conducted experiments based on that reading and her knowledge as one skilled in the art. Referring to the Declaration, it can be seen

that the tumor volume in Swiss nude mice was significantly inhibited by administration or treatment in multiple types of tumors. Thus, the Applicants respectfully submit that the experiments conducted in the Declaration in accordance with the teachings of the Applicants' Specification demonstrate, under oath, the *in vivo* efficacy of the composition recited in the Applicants' solicited claims.

The Applicants also enclose a Declaration of Professor Michel Jean Robert Perricaudet. Professor Perricaudet is thoroughly skilled in the gene therapy art and points out that Ms. Bouquet was able to conduct experiments based on a reading of the Specification, thereby confirming that the Applicants' Specification fully enables the solicited claims.

Of course, those skilled in the art can take those very same teachings and employ such teachings to treat the claimed hepatocarcinomas, mesenchymal tumors, neuroectodermal cancer, Ewing's sarcoma and malignant hemopathies as set forth in the solicited claims. Although some degree of experimentation would necessarily be required, that degree of experimentation, based on the teachings of the Applicants' Specification, would in no way be considered "undue." As a consequence, the Applicants respectfully submit that their Specification fully enables the solicited claims. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph is respectfully requested.

In light of the foregoing, the Applicants respectfully submit that the entire application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,



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